ALLERGY RELIEF-D- cetirizine hydrochloride and pseudoephedrine hydrochloride tablet, extended release CVS PHARMACY

Allergy Relief-D

Drug Facts

Active ingredients (in each extended-release tablet)	Purpose
Cetirizine HCl, USP 5 mg	Antihistamine
Decode a head in HCl HCD 130 mg	Nasal
Pseudoephedrine HCl, USP 120 mg	Decongestant

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - runny nose
 - sneezing
 - itchy, watery eyes
 - itching of nose or throat
 - nasal congestion
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

Warnings

Do not use

- if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- thyroid disease
- diabetes
- glaucoma
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- liver or kidney disease. Your doctor should determine if you need a different dose.

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

When using this product

- do not use more than directed
- drowsiness may occur
- avoid alcoholic drinks

- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- an allergic reaction to this product occurs. Seek medical help right away.
- you get nervous, dizzy, or sleepless
- symptoms do not improve within 7 days or are accompanied by fever

If pregnant or breast-feeding

- if breast-feeding: not recommended
- if pregnant: ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away at **1-800-222-1222.**

Directions

• do not break or chew tablet; swallow tablet whole

adults and children 12 years and over	take 1 tablet every 12 hours; do not take more than 2 tablets in 24 hours.
adults 65 years and over	ask a doctor
children under 12 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

- store between 20° to 25°C (68° to 77°F)
- do not use if carton is opened or if the blister unit is broken
- see side panel for batch number and expiration date

Inactive ingredients

hydroxyethyl cellulose, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, stearic acid, titanium dioxide

Imprinting Ink Contents: ammonium hydroxide, iron oxide black, isopropyl alcohol, N-butyl alcohol, propylene glycol, shellac glaze

Questions?

call toll free 1-800-818-4555 weekdays

Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895

PRINCIPAL DISPLAY PANEL - 12 Tablet Blister Pack Carton

CVSHealth_{TM}

Compare to the active ingredients in Zyrtec-D[®] 12Hr Tablets*

Indoor & Outdoor Allergies

Original Prescription Strength

NDC 69842-994-12

Allergy & Congestion

Allergy Relief-D

CETIRIZINE HYDROCHLORIDE & PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED-RELEASE TABLETS, USP

12 **HOUR**

5 mg/120 mg

Antihistamine; Nasal decongestant

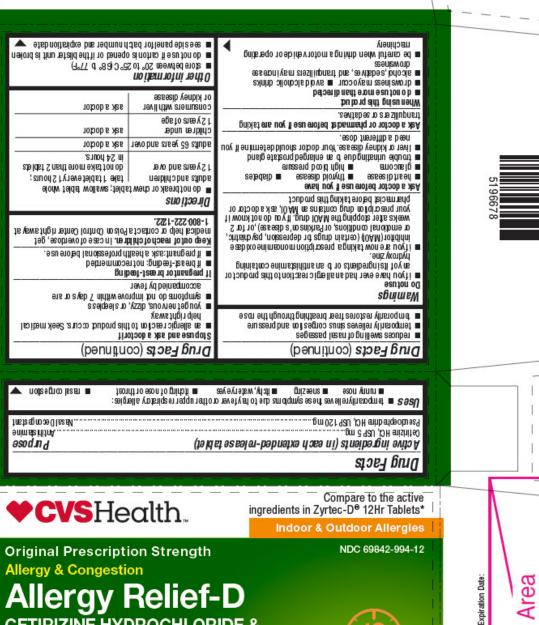
12 Hour Relief of:

Sneezing; Itchy, Watery Eyes; Runny Nose; Itchy Throat or Nose; Sinus

Pressure; Nasal Congestion

12 EXTENDED-RELEASE TABLETS

Actual Size





ergy Relief-D

RIZINE HYDROCHLORIDE & PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED-RELEASE TABLETS, USP

5 mg/120 mg

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#444385

Antihistamine; Nasal decongestant 12 Hour Relief of:

Sneezing; Itchy, Watery Eyes; Runny Nose; Itchy Throat or Nose; Sinus Pressure; Nasal Congestion

12 EXTENDED-RELEASE TABLETS



Batch No.

Actual Size

Questions? call toll free 1-800-818-4555 weekdays

Imprinting Ink Contents anmonium hydroxide, iron oxide black, isopropyl alcohol, N-bulyl alcohol, propylene glycol, shellac wice or ly stalline deliulose, steand act d, tranium dioxide Inac tive in gredients hy droxyethy cell ulose, hy droxypropy I cellulose, hypromellose, magnesium stearate, on Varnish Area

ALLERGY RELIEF-D

cetirizine hydrochloride and pseudoephedrine hydrochloride tablet, extended release

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-994	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CETIRIZINE HYDRO CHLO RIDE (UNII: 640047KTOA) (CETIRIZINE - UNII: YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 mg		
PSEUDO EPHEDRINE HYDRO CHLO RIDE (UNII: 6 V9 V2RYJ8 N) (PSEUDO EPHEDRINE - UNII:7CUC9 DDI9 F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg		

Inactive Ingredients					
Ingredient Name					
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)					
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)					
MAGNESIUM STEARATE (UNII: 70097M6I30)					
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)					
STEARIC ACID (UNII: 4ELV7Z65AP)					
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)					
AMMO NIA (UNII: 5138 Q 19 F1X)					
FERROSOFERRIC OXIDE (UNII: XM0M87F357)					
ISOPROPYL ALCOHOL (UNII: ND2M416302)					
BUTYL ALCOHOL (UNII: 8 PJ6 1P6 TS3)					
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)					
SHELLAC (UNII: 46 N10 7B71O)					

Product Characteristics				
Color	WHITE	Score	no score	
Shape	ROUND (Circular)	Size	9mm	
Flavor		Imprint Code	9 15	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69842-994-12	2 in 1 CARTON	06/30/2019		
1	6 in 1 BLISTER PACK; Type 0: Not a Combination Product				
2	NDC:69842-994-24	4 in 1 CARTON	06/30/2019		

6 in 1 BLISTER PACK; Type 0: Not a Combination Product				
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA090922	06/30/2019		

Labeler - CVS PHARMACY (062312574)

Establishment			
Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650445203	ANALYSIS(69842-994), MANUFACTURE(69842-994)

Revised: 5/2019 CVS PHARMACY